

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING)
PHARMACY, INC., PRODUCTS LIABILITY)
LITIGATION)
) MDL No.: 2419
) Master Docket No.: 1:13-md-2419-FDS
_____)
THIS DOCUMENT RELATES TO:)
)
_____)
All Actions Against St. Thomas Neurosurgical)

**PLAINTIFFS’ STEERING COMMITTEE’S SUPPLEMENTAL BRIEF CONCERNING
MOTION TO COMPEL COMPLIANCE WITH SUBPOENA TO MICHAEL O’NEAL
AND MOTION FOR PROTECTIVE ORDER OR, IN THE ALTERNATIVE,
MEMORANDUM IN SUPPORT OF MOTION *IN LIMINE* TO EXCLUDE REFERENCE
TO MICHAEL O’NEAL, O’NEAL’S PHARMACY CONSULTING SERVICES, AND ST.
THOMAS NEUROSURGICAL’S MEDICAL EXECUTIVE COMMITTEE**

In compliance with the Court’s December 22, 2015 Order (Dkt. 2534), the PSC submits this supplemental brief in support of the PSC’s Motion to Compel Compliance with Subpoena to Michael O’Neal (Dkt. No. 2437) and in opposition to O’Neal’s Motion for Protective Order (Dkt No. 2469). The PSC also submits this brief as a Memorandum in support of its contemporaneously filed Motion *in Limine* to Exclude References to Michael O’Neal, O’Neal’s Pharmacy Consulting Services, and St. Thomas Neurosurgical’s Medical Executive Committee.

On January 11, 2016, the PSC deposed Michael O’Neal on the three topics authorized by the Court in its December 22, 2016 Order (Dkt. No. 2534). The deposition testimony demonstrates two points: first, the Tennessee Quality Improvement Committee Privilege (“QICP”) should not apply to O’Neal’s consulting relationship with St. Thomas Neurosurgical, at least in part; second, if the Court finds that QICP precludes the PSC from conducting unfettered discovery of Mr. O’Neal’s relationship with St. Thomas Neurosurgical, there is a serious risk that St. Thomas Neurosurgical will utilize the QICP as both a sword and a shield at

trial. As to the second point, there are only two options to avoid unfairness, jury confusion, and severe prejudice to the plaintiffs: (1) authorize unlimited discovery of O’Neal, St. Thomas Neurosurgical, and the clinic’s Medical Executive Committee members, without regard to the QICP; or (2) exclude from trial any reference to Mr. O’Neal, Mr. O’Neal’s consulting services, and St. Thomas Neurosurgical’s Medical Executive Committee and its functions.

BACKGROUND

In its December 22, 2015 Order,¹ the Court issued an interim ruling concerning the PSC’s Motion to Compel and O’Neal’s corresponding Motion for Protective Order. (Dkt. No. 2534) The Court (1) held that O’Neal and St. Thomas Neurosurgical had not met their burden to establish that the Tennessee Peer Review Privilege (“PRP”) applied to Mr. O’Neal’s pre-April 12, 2011 activities; (2) reserved decision on whether the Quality Improvement Committee Privilege (“QICP”) applies retroactively to O’Neal activities before April 12, 2011²; (3) reserved decision on whether the QICP applies to O’Neal’s activities (regardless of time frame); (4) authorized a deposition of Mr. O’Neal to proceed only as to three specific topics, pending further order of the Court;³ (5) ordered Mr. O’Neal to produce a privilege log for any information related to NECC or St. Thomas Neurosurgical’s purchase of compounded MPA; and (5)

¹ The parties’ previous submissions concerning the Motion to Compel and Motion for Protective Order (Dkt. Nos. 2437-39, 2469, 2478, 2492, 2505, and 2541), the parties’ oral argument on December 17, 2015 (Dkt. No. 2543), and the Court’s December 22, 2015 Order (Dkt. No. 2534) set forth certain relevant facts and applicable legal standards concerning the QICP. The PSC incorporates its previous briefing and argument by reference.

² The PSC does not believe that a ruling on this issue is necessary for the Court to rule on the pending motion to compel compliance. To the extent the Court disagrees, the PSC addresses this issue in the attached Addendum.

³ The court limited questioning of Mr. O’Neal to the following three topics: “(1) questions about the contracts between STOPNC and O’Neal and O’Neal’s duties pursuant to those contracts; (2) questions about when the contracts were effective; and (3) questions about the alleged inconsistencies between the testimony of any witness and the contracts.” (Dkt. No. 2534 at p. 12.)

authorized the PSC to submit a supplemental brief within two weeks of O’Neal’s deposition regarding application of the QICP.

On January 5, 2016, Mr. O’Neal served a privilege log that listed just one document: a two page summary of Mr. O’Neal’s monthly medication management reviews for the year 2011.⁴

On January 11, 2016, the PSC took the deposition of Mr. O’Neal, subject to the Court’s restrictions.⁵ In most relevant part, O’Neal provided the following testimony:

- O’Neal is a licensed Tennessee pharmacist employed by Vanderbilt University Medical Center (“VUMC”).⁶ In an addition to his employment at VUMC, he provides pharmacy consulting services to 21 other facilities in the Nashville area, including St. Thomas Neurosurgical, to whom he has provided consulting services continuously since early 2007.⁷ He is not an employee of St. Thomas Neurosurgical.⁸
- The duties and pay structure set forth in O’Neal’s March 2007 contract with St. Thomas Neurosurgical (the “2007 Contract”) (attached hereto as Exhibit C) have remained the same, notwithstanding the fact that he executed a second contract with St. Thomas Neurosurgical in April 2013 (the “Second O’Neal Contract”) (attached hereto as Exhibit D).⁹
- During the course of his consulting relationship with St. Thomas Neurosurgical, O’Neal has performed monthly inspections of St. Thomas Neurosurgical relating to its medication management practices, including various “housekeeping” matters such as verifying inventory (assuring no diversion of product), ensuring that medications are stored appropriately and securely, and confirming that no

⁴ The privilege log, which was introduced during the O’Neal deposition as MDL Ex. No. 873, is attached as Exhibit A hereto.

⁵ A final transcript of the deposition of Mr. O’Neal is not yet available. All references herein are therefore to the rough transcript of Mr. O’Neal deposition, relevant excerpts of which are attached as Exhibit B hereto.

⁶ O’Neal Dep. at 14:9-16.

⁷ O’Neal Dep. at 14:24-15:9; 21:11-23.

⁸ O’Neal Dep. at 25:2-23.

⁹ See O’Neal Dep. at 77:12-17; 78:4-13; 79:15-17; 81:2-21; 94:21-95:13. At the deposition, counsel for St. Thomas Neurosurgical located a complete version of the Second O’Neal Contract (introduced at the deposition as MDL Deposition Exhibit 872) that contains no redactions other than O’Neal payment rate. For clarity of the record, the PSC has attached the 2007 Contract and the Second O’Neal Contract as Exhibit C and Exhibit D hereto, respectively.

out-of-date products remained on the shelves.¹⁰ Each month, O’Neal prepared a monthly report, in which he checked off whether the facility was compliant or non-compliant in these matters, and he sometimes provide an explanation for any non-complaint matters.¹¹ At the deposition, O’Neal produced a copy of a blank template of his monthly review report, which is attached hereto as Exhibit E.¹²

- O’Neal was also available to offer advice concerning on other pharmacy-related matters, such as procurement of drugs, but he typically provided additional information on these matters only when asked, or when he saw something through direct observation that he believed he should share with the facility.¹³
- O’Neal’s communications with St. Thomas Neurosurgical were limited to direct communications with Tina Sullivan (Debra Schamberg’s predecessor), Debra Schamberg, and perhaps one other nurse whose name O’Neal could not recall.¹⁴
- O’Neal has never attended a meeting of St. Thomas Neurosurgical’s Medical Executive Committee (“MEC”), he has never been asked to meet with the committee to discuss his findings, he has no knowledge as to who is on the MEC, he could not even affirmatively testify that St. Thomas Neurosurgical has a MEC, he has no specific knowledge as to whether Ms. Schamberg or Ms. Sullivan were members of a MEC, and he has never communicated directly with the purported MEC.¹⁵ The most O’Neal could say, in response to loaded questions from counsel for St. Thomas Neurosurgical, was to agree that his “understanding” was that his monthly reports would “end up in front the Medical Executive Committee in some form or fashion,” as part of some type of “rollup” document.¹⁶ When questioned by the PSC, O’Neal was unable to articulate specifics as to which of his notes or reports, if any, were actually reviewed by a MEC.¹⁷

¹⁰ O’Neal Dep. at 24:1-25:23.

¹¹ O’Neal Dep. at 42:16-45:13.

¹² Neither Mr. O’Neal nor St. Thomas Neurosurgical have produced copies of Mr. O’Neal’s actual monthly reports. The blank template was introduced as MDL Depo. Ex. 866.

¹³ *See, e.g.*, O’Neal Dep. at 28:2-9 (“If a client asks me about procurement of certain drugs, then I would provide that information.”); 80:7-22 (agreeing that he needed to be contacted first, “[u]nless I saw something through direct observation that I felt like I wanted to share with the facility”).

¹⁴ O’Neal Dep. at 46:12-22.

¹⁵ O’Neal Dep. at 46:7-8, 47:5-8, 47:13-17; 81:2-12; 100:22-101:1. In her 2013 affidavit, Debra Schamberg averred that O’Neal’s reports were utilized by St. Thomas Neurosurgical’s “Medical Executive Committee.” (*See* Dkt. No. 2439, Aff. of Benjamin A. Gastel, Ex. 5, Schamberg Aff. at ¶ 19). For clarity of the record, the PSC will utilize the same term herein.

¹⁶ O’Neal Dep. at 99:15-100:11; 101:2-6.

¹⁷ O’Neal Dep. at 112:9-113:3.

- St. Thomas Neurosurgical did not consult Mr. O’Neal prior to purchasing MPA from the New England Compounding Center.¹⁸ However, at some point in 2011, Mr. O’Neal became aware, through direct observation during his monthly inspections, that St. Thomas Neurosurgical had purchased MPA from NECC.¹⁹ Counsel for Mr. O’Neal directed Mr. O’Neal not to provide any additional information on this topic on the basis of the QICP, and counsel for St. Thomas Neurosurgical also objected on the basis of the QICP, asserting that “if there was any substantive discussion between him and STOPNC at any point about purchasing from compounders, purchasing from anybody frankly[,] it would be covered” by the QICP.²⁰
- Mr. O’Neal believes that he only possesses one document that he provided to St. Thomas Neurosurgical related to NECC or to MPA: the 2011 document listed on his privilege log. The exact nature of this document is unclear: counsel for O’Neal cut off O’Neal before he could explain what the document was, and stated that the two pages were “redacted out of something that he [O’Neal] did.” When the PSC asked a follow-up question in an attempt to determine what the document purported to be (without even addressing its substance), counsel for O’Neal cut off O’Neal again and told him: “Don’t say anything else.”²¹

In addition to O’Neal’s testimony, the Court should be aware of several other salient points related to St. Thomas Neurosurgical:

- St. Thomas Neurosurgical has yet to provide any details regarding the composition of its purported Medical Executive Committee.
- In a sworn interrogatory response, St. Thomas Neurosurgical did not identify O’Neal as an individual with whom it consulted at any point before purchasing MPA from NECC.²² This representation is consistent with O’Neal’s testimony. In another set of interrogatories, the PSC asked St. Thomas Neurosurgical to describe the extent to which St. Thomas Neurosurgical consulted with any pharmacist regarding whether to purchase medications from NECC in particular or compounding pharmacies in general. In response, St. Thomas Neurosurgical objected on the basis of the QICP and refused to provide a substantive answer.²³

¹⁸ O’Neal Dep. at 87:2-5; 88:2-18.

¹⁹ O’Neal Dep. at 86:12-87:5; 87:22-88:1.

²⁰ See generally, O’Neal Dep. at 83:1-86:10 (emphasis added).

²¹ O’Neal Dep. at 90:11-91:21.

²² See St. Thomas Neurosurgical’s Response to Interrogatory No. 2 of Plaintiff Frederick and Loduska May’s First Set of Interrogatories in *May, et al. v. St. Thomas Outpatient Neurosurgical*, 13C606 (originally filed in Tennessee Circuit Court, voluntarily dismissed, refiled, and consolidated into MDL 2419), attached as Ex. F hereto.

²³ See St. Thomas Neurosurgical’s Response to Interrogatory No. 14 of the PSC’s First Set of Interrogatories, attached as Exhibit G hereto.

- At deposition, invoking the QICP, Ms. Schamberg multiple times refused to answer questions related to St. Thomas Neurosurgical's purchases of compounded MPA from NECC as it related to Mr. O'Neal, including (1) whether she consulted with a pharmacist before sending lists of patient names to NECC; and (2) whether she consulted with Mr. O'Neal before purchasing from NECC.²⁴
- St. Thomas Neurosurgical also served a privilege log that asserted the QICP as a basis not to produce numerous entire categories of records.²⁵ Those categories included, among many other things, "All emails and documents to or from STOPNC's pharmacist consultant, Michael O'Neal, RPh related to his services as a pharmacy consultant."²⁶

APPLICATION OF THE TENNESSEE QUALITY IMPROVEMENT COMMITTEE PRIVILEGE

As the Court previously stated in its December 22, 2015 Order, the party asserting the privilege has the burden to establish that it applies.²⁷ Therefore, the burden is on O'Neal and St. Thomas Neurosurgical to establish that the QICP applies here; otherwise, the information sought from Mr. O'Neal is discoverable. Again, in ascertaining the scope of the QICP, Tennessee Supreme Court precedent requires the Court to construe the statute according to its plain meaning and, within the bounds of affording that plain meaning to the statute's terms, to construe the statute narrowly because the QICP is in derogation of the common law.²⁸

A. Saint Thomas Neurosurgical's "Quality Improvement Committee" Remains A Mystery

Under the QICP statute, a "Quality Improvement Committee" or "QIC" is defined as "a committee formed or retained by a healthcare organization, an activity of a healthcare

²⁴ See Excerpts of Transcript of Deposition of Debra Schamberg, attached as Exhibit H hereto, at 215:19-216:5; 277:11-279:9.

²⁵ See St. Thomas Neurosurgical Privilege Log, attached hereto as Exhibit I.

²⁶ As it relates to O'Neal, the privilege log does not identify specific documents – instead, it asserts blanket privilege over all communications with O'Neal, without specifying the date of each communication, the recipient, or the subject matter of the communication.

²⁷ Dkt. No. 2534, at p. 6

²⁸ *Lee Med.*, 312 S.W.3d at 525-26.

organization, or one (1) or more individuals employed by a health organization performing the types of functions listed in subdivisions (4)(A)-(P), the purpose of which, or one (1) of the purposes of which is to evaluate the safety, quality, processes, costs, appropriateness or necessity of healthcare services by performing functions including, but not limited to” one of 16 enumerated non-exclusive functions.²⁹ By its plain terms, a QIC must further one of the stated purposes and must be either (a) a “committee formed or retained by a healthcare organization,” (b) “an activity of a healthcare organization,” or (c) one or more individuals employed by a healthcare organization. Because O’Neal is not employed by St. Thomas Neurosurgical, an initial question is whether, individually, he meets either of the first two definitions of a QIC.

As to the first definition of a QIC, the QICP statute does not define the term “committee.” The Tennessee Supreme Court has held that, “in interpreting the meaning of a word in a statute, the court may utilize dictionary definitions.”³⁰ As defined in Black’s Law Dictionary, a committee is “a subordinate **group** to which a deliberative assembly or other organization refers business for consideration, investigation, oversight, or action.”³¹ Here, O’Neal is not a “committee” because he is a single person, not a “group.” Indeed, nothing in his testimony (either at deposition or by affidavit) indicates that he understood himself to constitute a “committee” under the QICP statute.

As to the second definition of a QIC, the statute indicates that a “QIC” is “an activity of a healthcare organization.” Read literally, this term would mean that **any activity** of a healthcare organization, even the generation of routine medical records (which on a common sense level

²⁹ Those functions are defined broadly, including, *inter alia*, the evaluation, review, or improvement of methods, procedures or treatment being utilized, and activities to determine the healthcare organization’s compliance with state or federal regulations. Tenn. Code Ann. § 68-11-272(b)(4)(L) and (O).

³⁰ *State v. Majors*, 318 S.W.3d 850, 859 (Tenn. 2010).

³¹ Black’s Law Dictionary (10th ed.) (emphasis added).

relate to patient safety and the appropriateness of medical care), would be privileged from civil disclosure. Moreover, it is nonsensical to define a “committee,” which is a group of persons, as an “activity,” which Black’s Law Dictionary defines as “[t]he collective acts of one person or of two or more people engaged in a common enterprise.” The PSC submits that this second definition of a committee is illogical, nonsensical, and should be disregarded. To the extent that the Court finds some coherence or limiting principle in the statutory language, the PSC submits that O’Neal did not constitute a QIC under this definition because he was not even aware that he was performing an “activity” under the QICP statute for St. Thomas Neurosurgical. The Court therefore should not regard Mr. O’Neal as a “QIC.”

In evaluating the application of the QIC here, the only potential “QIC” in the record is the purported Medical Executive Committee (“MEC”) at St. Thomas Neurosurgical, which is referenced in the Schamberg Affidavit. St. Thomas Neurosurgical has yet to identify the members of the MEC, and O’Neal had essentially no understanding regarding its existence, composition, and functions as it related to his consulting work. As best the PSC can discern, St. Thomas Neurosurgical takes the position that information provided by O’Neal to St. Thomas Neurosurgical (through Tina Sullivan, Debra Schamberg, or another nurse) constitutes information supplied to St. Thomas Neurosurgical’s QIC because it “ended up”, “in some or fashion,” before the MEC. The PSC will therefore analyze the remaining requirements of the QICP statute with that understanding.

B. Mr. O’Neal Did Not Provide or Produce “Records” of a QIC

The QICP statute provides that “[r]ecords of a QIC and testimony or statements by a healthcare organization’s officers, directors, trustees, healthcare providers, administrative staff, employees or other committee members or attendees relating to activities of the QIC shall be

confidential and privileged and shall be protected from direct or indirect means of discovery, subpoena, or admission into evidence in any judicial or administrative proceeding.”

Furthermore, “[a]ny person who supplies information, testifies or makes statements as part of a QIC may not be required to provide information as to the information, testimony or statements provided to or made before such a committee or opinions formed by such person as a result of committee participation.”³² In relevant part, the QICP statute defines “records” to mean “records of interviews and all reports, incident reports, statements, minutes, memoranda, charts, statistics, evaluations, critiques, test results, corrective actions, disciplinary actions, and any and all other documentation generated by or in connection with activities of a QIC”³³

Here, O’Neal does not know who composes the MEC at St. Thomas Neurosurgical, nor could he even testify affirmatively that St. Thomas Neurosurgical has a MEC in the first place. He also testified that he has never knowingly communicated directly with the MEC, has never attended a meeting of the MEC, and has never been called to discuss any of his reports or conclusions with the MEC. His original contract, which outlined duties that have never changed during the course of his consultancy with St. Thomas Neurosurgical, made no mention of a “peer review committee,” “medical review committee,” or “quality improvement committee.” Thus, his reports and communications with St. Thomas Neurosurgical (through Ms. Sullivan, Ms. Schamberg, or any other intermediary) do not – and never did – constitute “documentation generated by” the MEC or “documentation generated in connection with” the activities of the MEC. For the same reasons, Mr. O’Neal did not provide information, testimony, or statements “to or before” the MEC, nor did he participate in the MEC’s activities.

³² Tenn. Code Ann. § 68-11-272(c)(1).

³³ *Id.* at § 272(b)(5).

As to statements or testimony, the QICP only shields from disclosure testimony or statements “by a healthcare organization’s officers, directors, trustees, healthcare providers, administrative staff, employees or other committee members or attendees relating to activities of the QIC” – none of which apply to O’Neal.

C. Mr. O’Neal Provided Information From An “Original Source” Which Is Not Subject To The QICP

The QICP statute provides that “[a]ny information, documents or records, which are not produced for use by a QIC or which are not produced by persons acting on behalf of a QIC, and are otherwise available from original sources, shall not be construed as immune from discovery or use in any judicial or administrative proceedings merely because such information, documents, or records were presented during proceedings of such committee.”³⁴ Here, based on his own testimony, O’Neal did not knowingly produce documents “for use by a QIC”, nor was he acting “on behalf of a QIC” that he could not even identify or affirmatively state existed. He constituted an original source of information for the reports he generated and the information that he provided.

For these reasons, the Court should find that the QICP does not apply to Mr. O’Neal’s communications with St. Thomas Neurosurgical, and the Court should permit the PSC to conduct an unfettered deposition of Mr. O’Neal.

ALTERNATIVE MOTION IN LIMINE

To the extent that the Court holds that any aspects of O’Neal’s communications with St. Thomas Neurosurgical (as well as anything that St. Thomas Neurosurgical did with those communications) are privileged under the QICP, defendants cannot utilize the QICP as both a sword and a shield to selectively present evidence to the jury that the PSC has no means of

³⁴ *Id.* at § 272(c)(2).

rebutting or exploring before the jury. Furthermore, regardless of sword/shield doctrine, the presentation of limited evidence concerning Mr. O’Neal, his consulting relationship with St. Thomas Neurosurgical, and the Medical Executive Committee should be excluded under Fed. R. Evid. 403 because its probative value would be substantially outweighed by the dangers of unfair prejudice, jury confusion, and misleading the jury.

A. The Sword/Shield Doctrine and the At Issue/Implied Waiver/Fairness Doctrine

Courts universally recognize that it is improper to use an evidentiary privilege as both a “sword” and a “shield”, either by selectively waiving the privilege or by otherwise capitalizing on the opposing party’s inability to test or impeach assertions made at trial with respect to the subject matter of otherwise privileged material.³⁵ In effect, courts hold that a party waives a privilege entirely when it seeks at trial to rely on selective aspects of otherwise privileged information.³⁶

³⁵ See, e.g., *Columbia Data Prods. v. Autonomy Corp.*, Civil Action No. 11-1207-NMG, 2012 U.S. Dist. LEXIS 175920, at *52 (D. Mass. Dec. 12, 2012) (“[A] subject matter waiver of work product material is appropriate where a party is attempting to use otherwise protected information as ‘both a sword and a shield’ in order to gain an unfair tactical advantage over the opposing party.”) (quoting *In re Keeper of Records*, 348 F.3d 16, 24 (1st Cir. 2003)); *Boyd v. Comdata Network*, 88 S.W.3d 203, 226 (Tenn. Ct. App. 2002) (“Litigants may not use the work product doctrine as a sword and a shield. Thus, they may not selectively disclose a protected document to prove a point and then invoke the work product doctrine to prevent their opponent from challenging the assertion.”) (citation omitted); *Reitz v. City of Mt. Juliet*, 680 F. Supp. 2d 888, 893-94 (M.D. Tenn. 2010) (finding implied waiver, because “when a Title VI defendant raises a *Faragher-Ellerth* defense premised on an internal investigation, the defendants waives the attorney-client privilege and work-product protection for documents underlying the final investigative report – including interview memoranda authored by the investigator. Fairness dictates that the plaintiff be allowed to assess the full measure of the defendant’s response in light of what it learned from its investigation.”) (internal quotation and citation omitted).

³⁶ See, e.g., *Mass. Mut. Life Ins. v. Merrill Lynch, Pierce, Fenner & Smith*, 293 F.R.D. 244, 248 (D. Mass. 2013) (“It is well settled that waiver may be imposed when the privilege holder has attempted to use the privilege as both a sword and a shield.”) (internal quotations omitted); *Volpe v. U.S. Airways, Inc.*, 184 F.R.D. 672, 673 (M.D. Fla. 1998) (holding that, where defendant intended to rely on the fact of its internal investigation as a defense to sexual harassment claim

Similarly, courts, including this Court, agree that fairness considerations may require full discovery of otherwise privileged material “where the party asserting the privilege makes factual assertions, the truthfulness of which may be assessed only by an examination of the privileged communications or documents.”³⁷

Indeed, this Court has consistently followed the Second Circuit’s articulation of the fairness doctrine in *In re Erie*.³⁸ There, the Second Circuit reasoned that, “[u]nderlying any determination that a privilege should be forfeited is the notion of unfairness,” which implicates the “type of unfairness in litigation circumstances when a party uses an assertion of fact to influence the decisionmaker [sic] while denying its adversary access to privileged material potentially capable of rebutting the assertion.”³⁹

B. Background

1. The Shield

Both Mr. O’Neal and St. Thomas Neurosurgical take the position that the substance of **any** of their communications is privileged from disclosure under the QICP statute. In fact, throughout this litigation, St. Thomas Neurosurgical and Ms. Schamberg have consistently refused to provide substantive information concerning their communications with O’Neal. At his deposition, O’Neal testified that (1) he was not consulted before St. Thomas Neurosurgical

and sought to produce only the final report but not the investigative materials under the “self-critical analysis privilege,” the defendant had waived the privilege entirely and discovery of all materials was warranted).

³⁷ *Am. S.S. Owners. Mut. Prot. & Indem. Ass’n v. Alcoa S.S. Co.*, 232 F.R.D. 191, 199 (S.D.N.Y. 2005); *see also Greater Newburyport Clamshell Alliance v. Pub. Serv. Co. of N.H.*, 838 F.2d 13, 20 (1st Cir. 1988); *Banco de Brasil, S.A. v. 275 Wash. St. Corp.*, Civil Action No. 09-11343-NMG, 2011 U.S. Dist. LEXIS 82185, at *7 (D. Mass. July 27, 2011) (“An ‘at issue’ waiver of the attorney-client privilege occurs when a party implicitly waives the privilege, at least in part, by injecting certain types of claim or defenses into a case.”) (quotation omitted).

³⁸ *See, e.g., Bacchi v. Mass. Mut. Life Ins. Co.*, Civil Action No. 12-cv-11280-DJC, 2015 U.S. Dist. LEXIS 80552, at *11-15 (D. Mass. June 22, 2015) (collecting recent cases).

³⁹ *In Re Erie*, 546 F.3d 222, 229 (2d Cir. 2008).

before it purchased MPA from NECC, (2) he nevertheless was aware, through direct observation at some point during his monthly inspections, that St. Thomas Neurosurgical had purchased MPA from NECC, and (3) at some point in 2011, he communicated information to St. Thomas Neurosurgical regarding either NECC or the purchase of MPA (the PSC has no way of knowing which) that, in some fashion, may have been “rolled up” into a longer document.

At present, the QICP (and the Court’s previous order) precludes the PSC from ascertaining information concerning what O’Neal might have known, discovered, investigated, concluded, or communicated to St. Thomas Neurological regarding its purchases of MPA, its relationship to NECC, the risks of purchasing from a compounding pharmacy, and the like. Furthermore, O’Neal’s invocation of the QICP prevents the PSC from accessing the only document in his possession that he provided to St. Thomas Neurosurgical related to NECC or the purchase of MPA, Debra Schamberg refused to answer any questions regarding her communications with O’Neal, and the St. Thomas Clinic Defendants (including Schamberg and Dr. John Culclasure) have refused to provide any substantive information in their discovery responses and document productions related to Mr. O’Neal and the MEC.

In other words, at present, the substance of O’Neal’s relationship to St. Thomas Neurosurgical is a “black box.”

2. The Sword

Based on questioning by counsel for St. Thomas Neurosurgical at O’Neal’s deposition, the PSC anticipates that St. Thomas Neurosurgical will attempt to utilize the PSC’s inability to pierce the QICP as a means to gain a strategic, unfair, and severely prejudicial advantage at trial.

Specifically, the PSC anticipates that St. Thomas Neurosurgical will attempt to introduce the following facts to the jury: (1) that it was in a consulting relationship with Mr. O’Neal during

the time frame in which St. Thomas Neurosurgical purchased MPA from NECC; (2) that St. Thomas Neurosurgical retained Mr. O’Neal to serve as a pharmacy consultant to ensure that it was complying with all regulatory and industry standards regarding its pharmaceutical practices; and (3) that O’Neal was aware that St. Thomas Neurosurgical was purchasing MPA from NECC before the fungal meningitis outbreak. By introducing these facts, St. Thomas Neurosurgical could create the impression – which the PSC would have no adequate means of rebutting – that it met the relevant standard of care because O’Neal either blessed the clinic’s purchases of MPA from NECC or otherwise saw no problem with those purchases.

Introducing these facts would be manifestly unfair to the plaintiffs and would constitute an improper use of the QICP as both a sword and a shield. Absent unfettered discovery of Mr. O’Neal and the St. Thomas Clinic Defendants, the PSC would have no means at trial to rebut these facts or provide context for them. Indeed, it could be the case that Mr. O’Neal specifically directed St. Thomas Neurosurgical **not** to purchase MPA from a compounding pharmacy or from NECC specifically, otherwise **warned them** in some fashion, or was even **misled** by Ms. Schamberg or St. Thomas Neurosurgical. The PSC has no way of ascertaining the truth of these matters, no ability to gather information that would enable the PSC to impeach testimony from Mr. O’Neal or a St. Thomas Neurosurgical witness, and no way of rebutting whatever inferences the defendants would have the jury draw from the limited facts in the record concerning Mr. O’Neal. Under the circumstances, it would be unfair to permit St. Thomas Neurosurgical to capitalize on the “black box” of information that the QICP shields from disclosure.

C. The Potential Remedies

Unless both Mr. O’Neal and St. Thomas Neurosurgical are prepared to waive the QICP (to the extent that it applies) entirely as it relates to Mr. O’Neal, the Court is left with only two

options: (1) permit unfettered discovery of all entities who possess relevant information that has been withheld on the basis of the QICP (*i.e.*, impose a waiver of the privilege), or (2) exclude any references to Mr. O’Neal and the fact that St. Thomas Neurosurgical had retained a pharmacy consultant during the period in which it purchased MPA from NECC.

In order to probe the matters subject to the QICP sufficiently, the PSC would require at least the following relief: (1) an unrestricted deposition of Mr. O’Neal; (2) an unrestricted continuation of the common fact deposition of Ms. Schamberg; (3) production of the record over which Mr. O’Neal has claimed the QICP; (4) production of all records relating to Mr. O’Neal over which St. Thomas Neurosurgical claimed the QICP in its privilege log; and (5) depositions of all MEC Members (once identified) who received any information Mr. O’Neal related to the aforementioned topics. Discovery of this nature would require relief from the Court to conduct additional common discovery at a late stage in the proceedings, and would require the Court to force Mr. O’Neal and the St. Thomas Clinic Defendants to waive a statutory privilege involuntarily.

On the other hand, if the Court believes that the QICP does not permit implied waiver or that other concerns militate against permitting unfettered discovery by the PSC, the simple solution would be for the Court to exclude any references at trial to Mr. O’Neal, his consulting services, and the MEC. This is the approach that courts have taken when confronted with similar concerns about the subject matter of privileged material, including in the context of materials subject to a medical review or peer review privilege.⁴⁰

⁴⁰ See, *e.g.*, *Murphy v. Wood*, 667 P.2d 859, 866-67 (Idaho Ct. App. 1983) (finding that, where broad peer review privilege shielded defendant’s records from disclosure, exclusion of references or suggestions relating to peer review proceedings was justified, and that it would not be fair to permit any party to present a “distortion of the truth” at trial by presenting information that the other side could not rebut because of the privilege); *Bridenstine v. Giovanni*, CV075003067S,

D. Rule 403 Also Requires The Exclusion Of Information Concerning Mr. O’Neal’s Relationship With Saint Thomas Neurosurgical

Under Fed. R. Civ. P. 403, the Court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence. Here, regardless of the application of sword/shield doctrine and related fairness doctrines, evidence concerning Mr. O’Neal, his relationship to St. Thomas Neurosurgical, and the MEC should be excluded because any scant probative value would be substantially outweighed by unfair prejudice to the plaintiffs and confusing or misleading the jury concerning the underlying facts.

If the defendants are permitted to present (limited) non-privileged information regarding O’Neal and his relationship to St. Thomas Neurosurgical, it would create the impression that O’Neal was aware of St. Thomas Neurosurgical’s purchase of MPA, that O’Neal saw nothing wrong with those purchases and did not alert St. Thomas Neurosurgical of any issues, and that St. Thomas Neurosurgical complied with the standard of care by retaining Mr. O’Neal. As described in the previous section, it is impossible to know (in light of the privilege) what O’Neal knew about these issues and what, if anything, he communicated to St. Thomas Neurosurgical about them. Furthermore, the QICP prevents the PSC from discovering what discussions the MEC may have had regarding its purchases of MPA, and what information it communicated to Mr. O’Neal. Absent this information, the jury would be left to speculate about why the trial contained no substantive information regarding Mr. O’Neal’s communications or the MEC’s

2011 Conn. Super. LEXIS 1621, at *15-26 (Conn. Sup. Ct. June 28, 2011) (granting new trial, where defense counsel “carefully planned how to put” the fact of a peer review process before the jury and to suggest that the peer review process did not result in discipline, despite earlier order excluding all references to the peer review process in light of Connecticut’s peer review law).

deliberations, and the jury might even draw the conclusion that, if Mr. O’Neal had seen something wrong or that St. Thomas Neurosurgical had ignored a known pharmacy risk within Mr. O’Neal area of expertise, the plaintiffs would have presented that evidence at trial.

In sum, introducing evidence on these topics would be severely prejudicial to the PSC – which has no means of rebutting the inferences that the jury might draw. It could confuse or mislead the jury into drawing favorable inferences for the defendants when none are warranted (and when the actual underlying facts are unknown).

CONCLUSION

The Court should find that the QICP does not apply to the defendants’ relationship with O’Neal, at least in part. To the extent that any records or information related to Mr. O’Neal’s relationship with St. Thomas Neurosurgical or to the MEC are privileged, the Court should either permit unfettered discovery without regard to the QICP or, in the alternative, grant the PSC’s Motion in *Limine* to exclude all of that information at trial.

Date: January 25, 2016

Respectfully submitted:

/s/ Benjamin A. Gastel

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CERTIFICATE OF SERVICE

I, Benjamin A. Gastel, hereby certify that I caused a copy of the foregoing document to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Date: January 25, 2016

/s/ Benjamin A. Gastel
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